

**REMARKS**

Claims 1-4, 6-24, and 26-99 are now pending in this application. Claims 15 and 18-20 were rejected as indefinite under 35 U.S.C. 112, second paragraph. Claims 1-4, 6-24, 26-43 and 54-99 were rejected as obvious over U.S. Patent No. 5,605,696 to Eury et al. ("Eury") in view of U.S. Patent No. 4,304,767 to Heller, et al. ("Heller"). **Claims 18-20 and 44-53 were held to be allowable if amended so as to overcome the indefiniteness. Claim 18 is amended and placed in independent form. Claims 18-20 are now allowable.** Claims 45-53 are redundant as a result of amendments to claim 44 and thus are cancelled.

**Rejection under 35 U.S.C. 112**

The Examiner rejected claims 15 and 18-20 as indefinite on the basis that claim 18 has no definition for R and R<sub>1</sub> recited in the second polymer and claim 15 provides no basis for "the aliphatic diol" and "the alkylene glycols".

Claim 15 is amended to delete "the aliphatic diol" and "the alkylene glycols" and insert in place thereof "the aliphatic group" and (alkylene glycols", respectively, which have sufficient antecedent basis. Claim 15 is therefore definite.

Claim 18 is amended to include definitions of R and R<sub>1</sub> as recited in the first polymer. Claim 18 is therefore definite.

Claims 19 and 20, which were held indefinite on the basis of claim 18 being indefinite, are therefore definite.

Claim 99 is amended to provide antecedent basis for the diols recited therein and is definite.

**Rejection under 35 U.S.C. 103(a)**

Claims 1-4, 6-17, 21-24, 26-43, and 54-99 were rejected as obvious over U.S. Patent No. 5,605,696 to Eury et al. ("Eury") in view of U.S. Patent No. 4,304,767 to Heller, et al. ("Heller") on the basis that Eury describes a stent coated with a polymer that can be a polyorthoester and that Heller describes a general formula of a polyorthoester and some polyorthoester species with similar structures as the ones defined in the claims. The applicants respectfully disagree.

*The claimed invention*

The claims define an implantable device having a coating thereon formed of a polyorthoester that is a polycondensation product of a diketene, a polyol, and optionally a hydroxylated compound. The inventiveness of the article lies in the following two aspects: (1) a coating formed of (2) a specific polymeric material that includes at least a specific polyorthoester.

*The prior art*

Eury describes a drug loaded polymeric material containing a therapeutic drug that can be applied to a structure of an intravascular stent. At col. 4, lines 37-54, Eury states that the material can include a polyorthoester (line 52). Heller describes polymers formed of a di-ketene acetals and a polyols. The polymers are suitable as carriers or matrices for drug and other beneficial material agents used for therapeutic purposes (col. 1, lines 10-14). The polymers formed of the acetals and the polyols in Heller are sub-species of the polyorthoester mentioned in Eury.

However, there is no motivation to combine Eury with Heller. Under the U.S. patent law, prior to combine the teachings in different references, the Examiner has to show that there is motivation in the cited prior art reference for one of ordinary skill in the art to combine the

teachings of the two references (see 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998); see also MPEP § 2143.01). Here, to one of ordinary skill in the art, what is missing in Eury is the motivation to use a polyorthoester formed by polycondensation of a diketene and a polyol or diol as provided in Heller, and what is missing in Heller is the motivation to use the specific polyorthoester described therein to form a coating as described in Eury. The applicants respectfully submit that the Examiner failed to show this motivation.

Eury describes a drug loaded polymeric material for forming a coating on a stent. The polymeric material can be, among many different biodegradable polymers, a polyorthoester, a genus that may encompass millions of chemical species having many different structures and can be made from different starting materials by many different methods. Eury certainly does not provide any motivation for one of ordinary skill in the art to use the polymers described in Heller for forming a coating on a stent.

Heller, on the other hand, describes polyorthoesters formed of diketenes and polyols for forming drug delivery matrices or carriers. While a coating on a stent can have a drug included therein, a coating on a stent does not have to include a drug. Further, a coating, even if it includes a drug, would be a subset of matrices or carriers for the drug, which can take many different mechanical or physical forms, including a coating. Heller does not provide any motivation for one of ordinary skill in the art to use the polyorthoesters formed of diketenes and polyols described therein to form a coating on a stent as described in Eury.

Therefore, the Examiner failed to provide motivation for one of ordinary skill in the art to combine the teachings in Eury with those in Heller. As such, claim 1, which defines (1) a coating on an implantable device formed of (2) a polymer which is the polycondensation product

of a diketene and a diol defined therein, is non-obvious over Eury in light of Heller under 35 U.S.C. 103(a).

Claim 2 provides that the implantable device of claim 1 is a stent and is therefore non-obvious per the analysis of claim 1.

Claim 3 defines the polymer as one formed of a diketene defined therein. Per the discussion of claim 1, claim 3 is non-obvious over Eury in light of Heller.

Claim 4 defines the polymer as one formed of a diketene provided therein. Per the discussion of claim 1, claim 4 is non-obvious over Eury in light of Heller.

Claims 6-17 depend on claim 1 and define an article having a coating formed of a specific polymer as defined therein. Per the discussion of claim 1, claims 6-17 are non-obvious over Eury in light of Heller under 35 U.S.C. 103 (a).

Claims 21-24 and 26-34 provide methods for forming a coating on an implantable article by applying to the implantable device a polymer formed of diketene and a diol or polyol. Per the discussion of claim 1, claims 21-24 and 26-34 are non-obvious over Eury in light of Heller.

Claims 35-43 depend on claim 1 and define the coating of claim 1 as having a specific polyorthoester as defined therein. Per the discussion of claim 1, claims 35-43 are non-obvious over Eury in light of Heller.

Claim 44 is amended to incorporate the limitations of claims 1, 12 and 45-53 and pentable.

Claims 45-53 are cancelled.

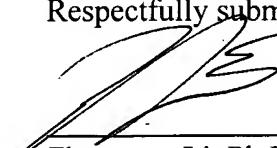
Claims 54-96 depend on claim 1 and define the coating of claim 1 as having a specific polyorthoester as defined therein. Per the discussion of claim 1, claims 54-96 are non-obvious over Eury in light of Heller.

Claims 97-99 define a medical article that comprises an implantable substrate having a coating formed of a specific polyorthoester defined therein. Per the discussion of claim 1, claims 97-99 are non-obvious over Eury in light of Heller.

Examination and allowance of the claims are respectfully requested. If the Examiner has any suggestions or amendments to the claims to place the claims in condition for allowance, applicant would prefer a telephone call to Zhaoyang Li for approval of an Examiner's amendment. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 393-9885

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Respectfully submitted,



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